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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,522

09/14/2004

Hidetoshi Hamamoto

2004-1425A

1134

513

7590

05/13/2010

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EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

NOTIFICATION DATE

DELIVERY MODE

05/13/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/507,522	<b>Applicant(s)</b> HAMAMOTO ET AL.	
	<b>Examiner</b> WALTER E. WEBB	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/27/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicants' arguments, filed 1/27/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103--previous***

Claim 1, 2, 6, 7 and 13-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mizobuchi et al. (WO 1998/058651 using US 6,268,355 as English Translation) in view of Knutson (US 4,401,651).

Applicant argues that it is important that the **preparation** be in a sol (uncrosslinked) state before use in order for the composition to absorb exudation in a wounded area of the skin. However, it is noted that the instant claims do not require the **preparation** to be in a sol state, but the water soluble polymer. Claim 1 clearly states, "the water soluble polymer in the preparation is in sol state before use, and then the water soluble polymer simultaneously shows phase transition to gel after the preparation absorbs exudation in a wounded area of the skin."

Applicant argues that the composition of Mizobuchi et al. is already in sol state prior to use and is therefore distinguished from the instant invention. In support of this conclusion applicant states that polyacrylic acid, unlike sodium polyacrylate, dissolves in glycerin. In doing so, the polyacrylic acid would react with the crosslinking agent to afford a gel. However, it appears that this based on pure speculation as there is no

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evidence presented that this reaction in fact takes place in the composition of Mizobuchi et al. Nevertheless, while polyacrylic acid is listed as an ingredient in Table 4, it is not the only water-soluble polymer. Polyvinylpyrrolidone, also a water-soluble polymer, is listed as an ingredient in the composition of Table 4, and meets the limitation of claim 1. This water-soluble polymer may be substituted with **sodium polyacrylate**, as per claim 6, insofar as Mizobuchi et al. recognizes their equivalency as viscosity increasers (see col. 3, lines 41-43). Mizobuchi et al. also recognizes the function of sodium polyacrylate as a water absorber insofar as it states "a high molecular weight compound being able to contain water, such as polyacrylate acid sodium" (see col. 3, lines 60-61). Even if the polyacrylic acid produces a gel, there is no reason to assume that the polyvinylpyrrolidone or sodium polyacrylate of Mizobuchi would not be able to show phase transition to gel after the preparation absorbs exudation in a wounded area of the skin.

Applicant takes the position that the term "ointment" in the preamble must be taken into consideration in determining the patentability over the prior art. However, it is noted that "ointment" has not been defined such that the composition of Mizobuchi et al. does not qualify. Applicant gives an example of an ointment composition in the specification at page 24, Table 2:

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Table 2

Ingredients	Preparation No. 4	Preparation No. 5
sodium polyacrylate	14	10
carmellose sodium	10	10
aluminum lactate		3
magnesium maluminometasilicate	1	
synthetic hydrotalcite	0.1	
white soft sugar	10	
potassium iodide	1	1
malic acid	1.4	
tartaric acid	2	2
iodine	1	1
macrogol	residue	residue

. It appears that the addition of macrogol is what qualifies the preparation as an ointment. If this is true, the composition of Table 4 of Mizobuchi et al. also qualifies as an "ointment" since it too comprises macrogol. At the moment, it is unclear how the recitation of "ointment" in the preamble necessarily limits the structure of the claimed composition such that the composition of Mizobuchi et al. fails to read on the instant claims. Applicant implies that "ointment" is equivalent to "sol state before use" (see Remarks pg. 6, last line). However, this would also imply that the powder formulation of the instant invention that is also described as "sol state before use" qualifies as an ointment.

Lastly, applicant argues that the present invention has "a superior property of being easily separated substantially as a mass after use" and that the gel material formed after use advantageously has a high strength as compared to a conventional gel preparation. However, the present invention has not been compared to the closest prior art. Since the composition of Mizobuchi et al. comprises a water-soluble polymer in an

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amount greater than 2% of the composition, it would reasonably be expected possess the properties recited above.

Even if, applicant's data supported an unexpected result, the instant claims are not commensurate in scope. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. It is not clear whether the results occur over the entire range of types of water-soluble polymers, crosslinking agents, sugars or fluidization agents.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612